

## **REMARKS**

### **Status of the Claims**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 23-25, 30-31, 40-63 and 66 are requested to be cancelled. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner.

Claims 16, 29, 35 and 64 are currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Exemplary support for the amendments to claims 16 and 64 is found in the specification on page 8, lines 2-5. Exemplary support for the amendment to claim 35 is found in the specification on page 5, line 30.

Upon entry of this Amendment, claims 16-22, 29, 32-39 and 64-65 will remain pending in the application.

### **Claim Objections**

The Examiner asserts that the numbering of the claims is not in accordance with 37 C.F.R. § 1.126. The Examiner asserts that misnumbered claims 58-61 submitted August 14, 2002 have been renumbered 62-66. Applicants have renumbered the claims as suggested by the Examiner. Therefore, Applicants respectfully request withdrawal of the objection.

**Issues Under Double Patenting**

The Examiner asserts that claims 62-66 are substantial duplicates of claims 58-61. Applicants have canceled claims 58-61. Therefore the rejection is moot. Applicants respectfully request withdrawal of the rejection.

**Claim Rejections - 35 U.S.C. § 112, Second Paragraph**

Claims 16-25, 29-41 and 46-66 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner asserts that in claim 16, the phrase “about 38 to about 43 amino acids...” is indeterminate and it is not clear where the deletion is. Applicants do not agree with the Examiner. However, in order to expedite prosecution, Applicants have deleted this phrase from claim 16. Claim 16, as amended, recites “[a] pharmaceutical composition comprising at least one HPV 16 L1ΔE7<sub>1-55</sub> fusion protein...” Exemplary support for this amendment is found on page 8, lines 2-5 of the specification.

The Examiner asserts that claims 23-28 and 40-57 remain vague and indefinite for the reasons of record because it cannot be discerned what is intended by a “deleted” L1 or E protein. Applicants do not agree with the Examiner. However, in order to expedite prosecution, Applicants have canceled claims 23-25 and 40-57. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants note that Applicants canceled claims 26-28 in their May 6, 2002 Amendment.

The Examiner asserts that claim 29 recites the limitation “font” in line 2. This is a clerical error. Applicants have amended claim 29 by replacing the term “font” with the term “the”. Applicants note that claim 29, as added in Applicants’ August 20, 2001 amendment correctly recited “the” instead of “font.”

**Claim Rejections - 35 U.S.C. § 112, First Paragraph**

**A. Written Description**

Claims 16-25, 29-41 and 46-66 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph for lack of written description. Applicants respectfully request reconsideration and withdrawal of the rejection.

1. The Examiner asserts that claims 16, 60 and 64 lack written description support because Applicant has not pointed to support for the phrase “about 38 to about 43 amino acids...” and the Examiner is unable to find support in the disclosure. Applicants have canceled claim 60. Therefore, the rejection with respect to claim 60 is moot. Applicants reserve the right to pursue the subject matter of the canceled claim in subsequent divisional applications. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner.

With respect to claim 16, Applicants do not agree with the Examiner. However, as discussed above, in order to expedite prosecution, Applicants have amended claim 16 to recite “[a] pharmaceutical composition comprising at least one HPV 16 L1ΔE7<sub>1-55</sub> fusion protein...”

Turning to claim 64, Applicants do not agree with the Examiner. However, in order to expedite prosecution, Applicants have amended claim 16 to recite “[a] method for producing a pharmaceutical composition comprising combining at least one HPV 16 L1ΔE7<sub>1-55</sub> fusion protein...”

2. The Examiner asserts that claims 16-25, 29-41 and 46-66 lack written description support because the claims are drawn to deleted or C-terminally deleted L1 or E proteins which have anywhere from 38-43 amino acids that have been deleted in unknown portions of the proteins. The Examiner asserts that the specification does not teach what structural elements are encompassed by these derivations or variants.

Applicants have canceled claims 23-25, 30, 31, 40-63 and 66, thus rendering the rejection of these claims moot. Applicants reserve the right to pursue the subject matter of

the canceled claims in subsequent divisional applications. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner.

With respect to claims 16-22, 29, 32-39, 64 and 65, as discussed above, in order to expedite prosecution, Applicants have amended claim 16 to recite “[a] pharmaceutical composition comprising at least one HPV 16 L1ΔE7<sub>1-55</sub> fusion protein...” Claims 17-22, 29, 32-39, 64 and 65 depend on claim 16. Therefore, claims 16-22, 29, 32-39, 64 and 65 comply with the written description requirements of 35 U.S.C. 112, first paragraph.

B. Enablement

Claims 16-25, 29-41 and 46-66 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph for lack of enablement. Applicants respectfully request reconsideration and withdrawal of the rejection.

The present specification provides sufficient enablement for a person of ordinary skill in the art to make and use the present invention. Attached herewith as Appendix 1 is a Declaration by Dr. John Nieland showing the reduction of tumor size and induction of T cell response in patients who were vaccinated with CVLPs consisting of the HPV 16 L1ΔE7<sub>1-55</sub> fusion protein, as compared to patients who were vaccinated with a placebo. This was a blind, placebo-controlled study of HPV 16-positive CIN II/III female patients. The results show a clear effect for CVLPs consisting of the HPV 16 L1ΔE7<sub>1-55</sub> fusion protein on HPV 16-positive CIN II/III female patients.

### CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 12/30/03

By Eve L. Frank

FOLEY & LARDNER  
Customer Number: 22428

Eve L. Frank  
Registration No. 46,785



22428

PATENT TRADEMARK OFFICE

Telephone: (202) 945-6142  
Facsimile: (202) 672-5399